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FILING DATE UNDER 35 USC 111.**

APPLICATION NUMBER: 60/530,014**FILING DATE: December 12, 2003**

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17607 U.S. PTO
121203

PTO/SB/16 (08-03)
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60/530014

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No.

INVENTOR(S)					
Given Name (first and middle [if any])		Family Name or Surname		Residence (City and either State or Foreign Country)	
ERAN		EILAT		HERZLIYA, ISRAEL	
Additional Inventors are being named on the _____ separately numbered sheets attached hereto					
TITLE OF THE INVENTION (500 characters max)					
INVENTION FOR THE TREATMENT OF EAR DISORDERS					
Direct all correspondence to: CORRESPONDENCE ADDRESS					
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<input checked="" type="checkbox"/> Firm or Individual Name: Dr. Eran Eilat					
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ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification Number of Pages: 6					
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Respectfully submitted,

[Page 1 of 2]

Date: December 11th 2003

SIGNATURE _____

REGISTRATION NO. _____

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USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

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Provisional Patent Application

To all whom it may concern

Be It Known That I Dr. Eran Eilat a citizen of Israel have invented a new and useful treatment of ear disorders with the use of medications in the form of mousse or foam.

December 1st, 2003

Invention for the treatment of Ear disorders

Field of the invention

The present invention related to a device that contains compounds known to treat ear disorders (such as infection of the external ear, ear pain, etc.) in the form of mousse or foam. Such a form could release active substance(s) slowly, enhance treatment effectiveness, increase compliance and could be more convenient than currently available ear medications.

Background

Acute otitis externa (AOE), known also as "swimmer's ear" affects 4 in every 1000 Americans annually ¹, and is reported to be one of the leading causes of physician visits due to ear pain².

Some risk factors associated with AOE include living in tropical or humid climates, summer season and swimmers or those who enjoy other water sports ^{2, 3} The warm and wet environment in the ear canal makes it an ideal location for bacteria to inhabit and proliferate. Additional risk factors include insertion of foreign objects into the ear canal, accumulation of cerumen (earwax), hearing aids, and some skin conditions (seborrhea, psoriasis, or eczema)⁴. Foreign objects such as cotton-tipped swabs or anything used to clean the ear may damage and scratch the ear canal, making the area susceptible to infection. The buildup of earwax and the use of hearing aids will decrease ventilation in the ear and keep the ear canal moist, increasing the

¹ Hannley MT, Denny JC, Holzer SS. Use of ototopical antibiotics in treating 3 common ear diseases. *Otolaryngol Head Neck Surg* 2000;116:934-940.

² LaRosa S. Primary Care Management of otitis externa. *Nurse Pract* 1998;23:125-133.

³ Pelton SI, Klein JO. The draining ear. Otitis media and otitis externa. *Infect Dis Clin North Am* 1988;2:117-129.

⁴ Biedlingmaier JF. Two ear problems you may not need to refer. *Postgrad Med* 1994;96:141-148.

chances of developing AOE. Preventive measures to avoid the risk of AOE include keeping the ear canal clean and dry, using earplugs while swimming, avoiding cleaning or scratching ears with cotton-tipped swabs and avoiding shower heads with powerful streams of water directed to the ear canal².

Current management of AOE includes cleaning the ear canal and administering topical drops. Topical treatments have the advantage of avoiding systemic side effects, enhancing patient compliance, and maximizing treatment outcomes. Initial therapy for AOE is typically an aminoglycoside combination consisting of neomycin, polymixin B and steroid (hydrocortisone, dexamethasone , etc.) (Cortisporin, Dex-Otic, etc.) ⁵. Current medications also includes quinolones derivatives i.e. Ciprofloxacin 1% or Ofloxacin 0.3%.

Another, but not limiting example of common use of ear drops is for ear pain treatment. Ear pain (otalgia) can range from mild discomfort or a feeling of fullness to severe, intense pain. Often ear pain results from conditions of the outer or middle ear. Ear pain usually results from conditions that may be caused by infection, trauma, or blockage of the ear. There are many possible causes of ear pain, including: trauma to the ear, including damage caused by use of cotton swabs sudden changes in pressure, such as changes in altitude when flying blockage of the ear canal from earwax or foreign object otitis externa, or swimmer's ear acute otitis media, or an infection of the inner ear mastoiditis, which is a serious bacterial infection of the bone behind the ear allergic reactions and allergies ruptured eardrum acute sinusitis or chronic sinusitis tooth abscess sore throat with referred pain to the ears Meniere's disease, which is a disorder of the inner ear tumors of the ear, which may be cancerous or benign temporomandibular joint syndrome

Ear pain, especially in children, can be very unpleasant and discomforting. There are several methods to treat ear pain; one of them is by using ear drops based on analgesics. Currently available medications includes, but not limited to, solutions that contains 20% Benzocaine, other analgesic and/or antipyrin.

⁵ Lee I, Steinberg I, Gill MA. Management of Ear Infections. Cal Parma 2001;spring; 56-64

Ear drops are used for the treatment of pain, inflammatory and infections of the ears. Those drops are applied by tilting head to the side, instilling drops of the medication into the ear and maintain the adopted position for a few minutes in order to allow the medicine to reach the interior of the ear. A clean cotton-wool plug may be inserted into the opening of the ear to prevent the medication from leaking out.

To prevent contamination of the ear drops, the bottle tip must not come into contact with any surface, including the hands and the ear itself.

The main disadvantages of the current solutions are that:

1. The current medications are in the ear canal for a short period of time since they are naturally washed out.
2. The current medication are difficult to apply for children who do not tend to cooperate mainly do the pain from the affected ear and their disability to maintain a position for prolonged periods (several minutes).
3. If a cotton wool is added to the ear it might be pushed inside the ear canal and difficult to take out, and could be irritating and annoying.

Description of preferred embodiment

The medication

The preferred embodiment is a medication for the treatment of acute otitis externa (AOE), otalgia or any other condition that requires application of any kind of medication into the ear canal. In the preferred embodiment, the medication is inserted in the form of foam or mousse. These forms allow prolonged contact of the active agent/s with the surface of the ear canal. This prolonged contact allows non-frequent applications (e.g. once or twice a day), shortening of healing period, since active compounds are in contact with affected area for longer periods which allow more rapid healing.

In a preferred, but un-limiting, embodiment of the current invention medication combination of two or more of the following which consisting of neomycin (or other aminoglycoside), polymixin B (or another anti-fungal agent), ciprofloxacin, ofloxacin, Oxytetracycline, nystatin Colistin sulfate or any other antibiotic/ antibacterial/ anti-fungal and/or steroid derivate (hydrocortisone, betamethasone dexamethasone , etc.) (Which could be in water or oil based solution) in the form of mousse or foam could be used for the treatment of AOE.

In another, but un-limiting, embodiment of the current invention medication based on benzocaine, amethocaine, tetracaine or other analgesic or combination with one of the above (anti-infective, steroid) at any concentration in the form of mousse or foam could be used for the treatment of otalgia.

The device

In another, but un-limiting, embodiment of the current invention the mouse or foam form of the medication as discussed above, shall be packed under pressure in aluminum tube, the outlet will be in a pipe form to ease ear access. As shown in drawing 1 the device could be composed of two parts; one is the container which contain the medication formulation, when pressed the medication is ejected in the form of mouss or foam. The second part is a pipe that leads the mouse or foam toward the ear.

Advantageous of th current invention

1. The foam or mousse forms could be applied infrequently (e.g. once daily) as opposed to frequent applications (3-6 times a day).
2. The use of the preferred embodiment dispenses the use of a cotton wool use, which could lead to deep insertion of the cotton, and the need for a trained physician to pull it out.
3. The application of the current invention is easier for children and does not require special position (i.e. head tilting for several minutes).
4. The foam or mousse forms will be evaporate spontaneously after a certain period of time (e.g. after around 2-24 hours), which could be predetermined in formulation.

Drawing 1:

